1.66 In the case of optional transfers under paragraph 1.59(d) or (e), the validation date remains the date on which it was first received by the REC that transfers the application.

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Re-allocation of transferred applications

1.67 Where a transfer is to take place, the Co-ordinator of the receiving REC should notify the applicant by phone or e-mail, explaining why the REC is unable to review the application. The applicant should be advised of the arrangements required for re-allocation.

1.68 Applicants should contact CAS about the re-allocation of any application relating to:

- Clinical trials of investigational medicinal products
- Multi-site studies to be conducted in two or more domains
- Prisoners
- Adults with incapacity in Scotland.

1.69 Applicants should contact the OREC Manager for advice on the re-allocation of applications requiring special expertise not available to the receiving REC.

1.70 In all other cases, the REC Co-ordinator should advise the applicant to approach another REC within the domain, and provide the relevant contact details and meeting schedules. If no REC within the domain is able to accept the application, or there is no REC established within the domain, the OREC Manager should refer the applicant to a REC in another domain within the OREC area or exceptionally within another OREC area.

1.71 Once the new allocation has been confirmed on RED, the electronic version of the application form will automatically be transferred. The Co-ordinator of the receiving REC should offer to forward the signed paper copy (if applicable) and the supporting documentation to the second REC.

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Responsibility for validating transferred applications

1.72 Responsibility for validating a transferred application passes to the Co-ordinator of the second REC.

1.73 The Co-ordinator of the second REC should notify the applicant whether or not it is valid as soon as possible, and normally within two working days of the arrival of the transferred documentation. Where the receiving REC had already issued a validation letter before deciding on the need for transfer, a second validation letter should be sent. The letter should carry the new REC reference number. Where the application is re-allocated to the first available meeting of another REC, the validation date remains the original date of receipt by the receiving REC. However, where the Chief Investigator has declined this option in favour of his/her preferred REC, the validation date is the closing date for the meeting of the preferred REC.

1.74 It is recommended that, wherever possible, the Co-ordinator of the receiving REC should make an initial assessment of the validity of the application before a transfer takes place. Where the application is clearly invalid, the applicant may be notified using SL3 and advised to submit a new application. This will avoid the need to transfer the documentation at this stage. Where the application appears to be valid, the Co-ordinator of the receiving REC may pass on this advice by phone or e-mail to the Co-ordinator of the second REC. This will enable the second Co-ordinator to issue the validation letter as soon as the documentation is received.

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Retention of SSI Form by local REC for lead site

1.75 Where the receiving REC is the local REC for the lead site and has received a SSI form with the application, this should be retained together with a copy of the Principal Investigator's CV. The local REC continues to be responsible for the site-specific assessment.

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Revision of applications following submission

1.76 In general, revisions should not be accepted, prior to the REC meeting, to an application that has been validated and booked for review.

1.77 If the applicant considers it necessary to make significant revisions to the application form or the supporting documentation prior to review by the REC, he/she should withdraw the application (see paragraph 1.82). Any minor revisions may either be discussed at the meeting or dealt with later in accordance with paragraph 1.78.

1.78 If the applicant considers it necessary to make minor revisions to the application form or the supporting documentation following review by the REC but before a final ethical opinion has been given, these may be included in the applicant's response to the request made by the REC for further information or clarification (see Section 3). The changes should be clearly highlighted, and the relevant documents given a new version number and date. At the discretion of the Chair, the revisions may then be reviewed in accordance with the procedures agreed for considering further information from the applicant.

1.79 If the Chair considers the proposed revisions to be both significant and unrelated to the matters raised by the REC in the ethical review, the applicant may be advised to withdraw the application and re-submit it. Alternatively, the application may be rejected. It is not appropriate at this stage for the applicant to introduce significant new issues, which the REC will not have had the opportunity to review collectively.

1.80 When considering revisions to applications for multi-site studies requiring SSA, the main REC should also note the guidance in paragraph 4.73.

1.81 For revisions made after a favourable opinion has been given, refer to the procedures for review of amendments in Section 5. "Notice of amendment" forms should not be used until after a favourable opinion has been given.

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Withdrawal of applications

1.82 If an applicant withdraws an application at any time, it should be treated as no longer valid. Letter SL26 should be sent to the applicant. If the applicant wishes to re-submit the application, it should be re-booked with the REC or through CAS, as appropriate. A new REC reference number should be issued. A new period of 60 days commences when the valid application is re-submitted.

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Applications not within the scope of a NHS REC

1.83 Where an application is received by a REC that falls outside the scope of a NHS REC as defined in GAfREC, the following procedures apply.

1.84 If the application relates to research in the field of health or social care, which (a) is not a CTIMP *and* (b) is outside the normal remit of a NHS REC as defined in GAfREC[1], the REC is not obliged to review it. However, it is desirable as a matter of public policy that such research is ethically reviewed, and RECs are encouraged to agree to review applications and give an ethical opinion on a voluntary basis. It is a matter for the Chair to decide whether the application should be reviewed. Applicants are encouraged to seek the advice of the REC prior to completing the application. Where the Chair agrees to review the application, it should be reviewed in accordance with standard operating procedures. In responding to the applicant following the meeting, SL25 should be used. Where the Chair declines to review the application, the following procedures apply:

[1] Where an application relates to a CTIMP, a NHS REC that is recognised by UKECA to review the appropriate class of CTIMP is generally obliged to review it even where the research is outside the scope of GAfREC.

- If the booking was made direct to a REC, the applicant may approach the OREC Manager, who will decide whether or not to invite another REC within the domain to consider the application.
- If the booking was made through CAS, the Operations Director will decide whether or not to invite another REC to consider the application.

1.85 If the application relates to a project that does not fall within the definition of research given in GAfREC, the Chair may decide that the application does not need to be submitted to a meeting of the REC. Where an application has been received to which this could apply, the Co-ordinator should send it to the Chair, who should consider the matter within 5 working days and notify the Co-ordinator whether or not it should be reviewed. If it is decided that the application does not require review, a response should be sent to the applicant using SL24. The REC is not responsible for giving an ethical opinion on the project. If, however, the application requires review, it should be validated and reviewed in the normal way.

1.86 Where the Chair or Co-ordinator is approached for advice on whether a project falls within the definition of research, and therefore whether an application should be submitted to the REC, it is recommended that the applicant is invited to provide a brief outline of the project in writing. This should then be considered by the Chair in line with the procedure in paragraph 1.85, except that the need to decide within 5 working days does not apply as no application has been submitted.

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Retrospective applications

1.87 In some cases, applicants may disclose that the research has already started without first obtaining a favourable ethical opinion. Within the NHS, this is a breach of research governance. In the case of a CTIMP, a criminal offence may also have been committed. All such cases should therefore be reported to the OREC Manager and the REC's appointing authority in accordance with the procedures in paragraphs 9.89-9.91.

1.88 Such applications should be considered invalid, and the REC is not obliged to proceed with any form of ethical review. An ethical opinion cannot be given

retrospectively. However, the REC has the discretion to consider the protocol and any other available documentation and to issue a letter to the applicant giving ethical advice about the project. The Chair may deal with the matter personally or the project may be considered at a meeting of the Committee or sub-committee.

1.89 If the applicant terminates the research and then submits a valid application to start a new project, this may be reviewed in the normal way, taking account of any concerns about the suitability of the investigator.

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Section 2: Meetings of a Research Ethics Committee

Summary

An ethical opinion can only be given after review of an application at a REC meeting. RECs normally meet monthly. There must be at least 10 scheduled meetings each year. Additional meetings can be arranged, particularly if there is a risk of not processing an application within the 60 day deadline.

Meeting schedules and closing dates for applications are agreed with a Committee's OREC Manager and then publicised to NHS organisations and research bodies. Schedules for recognised RECs are provided to the Central Allocation System (CAS).

The Co-ordinator arranges distribution of agenda, applications and other papers for meetings in accordance with local procedures. There should normally be a minimum of 5 and a maximum of 10 new applications for review at each meeting. The Co-ordinator should notify members in writing of business conducted outside the meeting and circulate copies of sub-committee minutes.

Under the Clinical Trials Regulations a quorum must be present before discussion of new applications can commence. A record of attendance should be kept. A quorum is 7 members including the Chair or a vice-chair, one lay and one expert member. Deputy members may attend in place of an expert member. A maximum of two former members or members of other ethics committees may be co-opted at each meeting. Attendance of observers is at the Committee's discretion and subject to a confidentiality agreement.

Members must declare any interests they have in relation to a study, either at or before the meeting. A REC cannot review a new application on which one of its own members or deputy members is named as an investigator. The Committee has discretion in dealing with other declared interests. Guidance is given on possible courses of action.

The Chief Investigator should be invited to the meeting to respond directly to any comments or questions raised by the committee. Attendance is not compulsory, however, and if an investigator is unable to attend this should not prejudice the decision of the committee. Supervisors of student researchers may also be invited to attend.

Members who are unable to attend may send written comments prior to the meeting.

Committees usually appoint a lead reviewer(s) for each application to review it in greater detail and lead the discussion at the meeting. Lead reviewers receive a copy of the full protocol for the study as well as other papers.

RECs may seek the advice of a specialist referee, for example when reviewing studies that involve minors or adults incapable of giving informed consent. The REC can ask for written advice before or after the meeting, or invite the referee to the meeting.

The meeting is chaired either by the Chair, or if s/he is not available the vice-chair or alternate vice-chair. All members must be given appropriate opportunity to express their opinion and the meeting should attempt to reach a unanimous decision.

Guidance is given to Co-ordinators on minute-taking. The minutes should be ratified by the Committee at the next meeting. The ethical opinion given on each application should be made public in the Committee's annual report.

Section 2 Meetings of a Research Ethics Committee

General policy

2.1 All valid applications for an ethical opinion should be reviewed at a meeting of a REC held in accordance with the following procedures, except where the expedited process described in Section 8 applies.

2.2 Procedures relating to the outcome of the ethical review, including the decisions available at meetings and the request for further information or clarification following the meeting, are set out in Section 3.

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Meeting schedules

2.3 A REC should hold at least 10 scheduled Committee meetings in each year for the purposes of ethical review of applications. Additional meetings may be held where necessary to ensure that an ethical opinion on an application is given within the time limit of 60 days from the date of receipt; or to discuss matters relating to the establishment or operating procedures of the REC; or for training purposes.

2.4 Meetings to review applications should normally be held at intervals of one month. A longer interval is permissible when meetings span holiday periods but should not at any time exceed two months.

2.5 OREC Managers should ensure that the meeting schedules of RECs in their areas are appropriately staggered, in particular over the holiday periods, to ensure that it is possible for any valid application to be reviewed within 60 days.

2.6 The schedule of Committee meetings for the year commencing on 1 April should be agreed between the Co-ordinator and the OREC Manager by 30 September in the previous year. The schedule should set out the dates, times and venues of meetings, and the closing date for applications to each meeting. All members and deputy members of the REC should be issued with details of the schedule.

2.7 The closing dates for applications should normally be no earlier than 21 days and no later than 14 days prior to each REC meeting.

2.8 Following approval by the OREC Manager, REC Co-ordinators should arrange for their meeting schedules to be widely publicised to NHS organisations and other research bodies based in the area covered by the REC. The information publicised should include at least the dates of REC meetings and the closing dates for receipt of applications. Any changes made to the meeting schedule during the year should be similarly publicised. There is no requirement to publicise arrangements for sub-committee meetings.

2.9 The Co-ordinators of recognised RECs should also notify the Operations Director and CAS of their meeting schedule for the forthcoming year and any changes made during the year. The Operations Director may request changes to meeting schedules to ensure that the system as a whole has sufficient operational capacity at all times.

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Agenda

2.10 The REC Co-ordinator should prepare the agenda for the meeting, which should include at least the following:

- The date, time and venue of the meeting
- Declarations of interest relating to items on the agenda
- Minutes of the previous Committee meeting
- Matters arising at the previous meeting(s) that the Committee specifically indicated that it wished to consider again
- Applications for ethical review to be considered at the meeting
- Report by the Co-ordinator (see paragraphs 2.15-2.20).

2.11 Where it is the local procedure to appoint lead reviewers (see paragraphs 2.21-2.22), the agenda should indicate the lead reviewer(s) for each application.

2.12 The agenda may also include discussion of the following where appropriate:

- General ethical issues, for example arising from new guidelines or recent publications
- Matters relating to the establishment or membership of the REC
- Matters relating to Committee procedures
- Training issues.

2.13 It is important that REC meetings include sufficient applications to maintain the expertise of the Committee and justify the resources involved, but not so many as to undermine the rigour of the ethical review. The agenda should normally include no fewer than 5 and no more than 10 new applications for ethical review. The local operating limits should be agreed with the OREC Manager. OREC Managers will review the workload of RECs periodically.

2.14 Section 6 describes arrangements for REC business that may be conducted by sub-committees. The agenda for Committee meetings may include items that would normally be reviewed in sub-committee, in particular where the Chair considers it important that a wider discussion takes place. In allocating business between the Committee and sub-committee meetings, the Co-ordinator and the Chair should weigh carefully the requirement to give ethical opinions within statutory time limits, the need to conduct REC business both efficiently and with due care, and the overall demands of the agenda on members.

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Report by the Co-ordinator

2.15 Members should be notified in writing of business undertaken outside REC meetings, including at least the following:

- Decisions or actions taken by Committee officers or members under delegated authority (see paragraph 2.17)
- Decisions taken by a sub-committee (the sub-committee minutes may be appended to the Co-ordinator's report or copied to members separately)
- Progress reports on research with a favourable opinion (see paragraph 9.14)

- Receipt of quarterly or annual safety reports on CTIMPs, and reports of Data Monitoring Committees (see paragraph 9.48)
- Notification of the conclusion or early termination of research (see paragraph 9.76)
- Receipt of final study reports (see paragraph 9.87).

2.16 It is recommended that the Co-ordinator should prepare a separate report for distribution to members with the papers for each meeting. However, it is a matter for the discretion of the REC how the information is reported, provided that it is in writing. Local procedures should be agreed. A standard report format will be made available on RED for optional use.

2.17 Where the REC has previously delegated authority to the Chair to issue the opinion of the Committee following receipt of further information or clarification from the applicant (see paragraphs 3.23-3.26), it should be notified once the opinion has been issued. The following information should be provided in the report:

- The ethical opinion given on the application
- The members that were involved in considering the further information.

2.18 Where an unfavourable opinion was given, it may be of interest to members to have a brief summary of the applicant's response, highlighting the points that failed to meet the Committee's requirements.

2.19 The Co-ordinator's report should normally be distributed with the main papers for the meeting, but may be circulated nearer to the date of the meeting. Once the report has been finalised, any further business that takes place prior to the meeting may be deferred to the report for the following meeting. Where exceptionally the Chair or Co-ordinator considers it essential that a matter is reported to the Committee as soon as possible, a further written report may be prepared or an oral report made to the meeting.

2.20 The Co-ordinator's report is mainly for the information of members and should not normally require detailed discussion. The decisions taken by Committee officers or members on behalf of the REC, or by sub-committees, do not need to be ratified by the REC. However, members should be allowed to raise any concern about the

decisions taken on their behalf, or about information received on the progress or safety of research. Any such concerns should be considered by the Committee and recorded in the minutes.

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Lead reviewers

2.21 A REC may appoint one or more members as lead reviewers for each application.

2.22 The specific role undertaken by lead reviewers both at the meeting and following the meeting is a matter for the discretion of the REC. Local procedures should be discussed and agreed by the members.

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Distribution of papers for meetings

2.23 The REC Co-ordinator should normally arrange for distribution of the agenda and papers for review at the meeting between 7 and 14 days prior to the meeting. Papers for the information of members may be distributed nearer to the date of the meeting or, exceptionally, tabled at the meeting. Under no circumstances should full applications be tabled at the meeting. The local requirements for distribution of papers should be discussed and agreed by the Committee.

2.24 All members should receive the application form for each new application, together with all supporting documentation except as follows:

- The protocol for the study should be sent only to the lead reviewer(s) and to members with relevant expertise. Other members should not normally need to see the protocol but should be provided with a copy if they request it.
- The Investigator Brochure for an investigational medicinal product should be sent only to members with relevant expertise (in particular, to the pharmacist or clinical pharmacologist).

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Attendance of the Chief Investigator

2.25 The Chief Investigator should be invited to attend the meeting at which his/her application is to be reviewed. The purpose of this is to be available to respond directly to requests from the Committee for further information, clarification or reassurance. In this way, many issues of concern to the Committee may be resolved at the meeting. Even where further consideration needs to be given by the Chief Investigator after the meeting to matters raised by the Committee, his/her attendance to hear the points raised in person may well prove to have been helpful in formulating a satisfactory response.

2.26 It is however not compulsory for the Chief Investigator to attend, and consideration of the application should not be prejudiced if he/she is unable or unwilling to attend.

2.27 Where the Chief Investigator is unable to attend, it is acceptable for another key investigator or collaborator to attend instead. It is not generally acceptable for a representative of the sponsor to attend in place of the Chief Investigator, but the Chair may allow this in exceptional circumstances. Other members of the research team or representatives of the sponsor may also express an interest in attending alongside the Chief Investigator, and this should normally be permitted if the size of the meeting room makes it practicable.

2.28 Where speakerphone facilities are available in the room to be used for the meeting, the REC may offer the Chief Investigator the alternative of being available by phone at the time of the review. It should be possible for all members present in the room to question the Chief Investigator and hear the responses.

2.29 In the case of applications submitted by students, the REC should consider inviting the educational supervisor to attend. In addition, where the student is conducting the research under supervision within the NHS, the clinical supervisor may be invited to attend.

2.30 It is not the purpose of the Chief Investigator's attendance to make a formal presentation of the study, and this should not be permitted.

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Quorum requirements and meeting attendance

2.31 The quorum for meetings of a REC is seven members, including at least the following:

- The Chair *or*, if unavailable, the vice-Chair or alternate vice-Chair
- One lay member[1]
- One expert member.

2.32 A deputy member who is attending in place of their "lead" member should be counted for the purpose of the quorum.

2.33 A co-opted member (see paragraphs 2.40-2.42) should also be counted for the purpose of the quorum.

2.34 The following should not be counted for the purpose of the quorum:

- The Committee Co-ordinator
- Advisers or referees
- Members who are yet to arrive at the meeting, or who have left early
- Members who submit written comments but do not attend
- Deputy members attending alongside the lead member.

2.35 Where a quorum is not present, the Committee may not commence, continue or conclude any discussion with the purpose of determining the Committee's opinion on an application for ethical review.

2.36 A Committee meeting, or part of the meeting, at which a quorum of members is not present, may proceed with any other business on the agenda as if it were a sub-committee meeting, provided that the Chair (or vice-Chair or alternate vice-Chair) and at least one other member is present.

[1] The definition of expert and lay members is defined in the Clinical Trials Regulations. Detailed guidance is given in the paper "Membership of recognised RECs", available on the NRES website.

2.37 The Co-ordinator should keep a record of attendance, indicating which members and deputy members were present for the discussion of each application for ethical review.

2.38 Where the Co-ordinator of a REC is concerned that a forthcoming meeting may not be attended by a quorum of members due to foreseen absences, he/she should consider the following options with the OREC Manager:

- Co-opting up to two additional members (see paragraphs 2.40-2.42)
- Postponing and re-arranging the meeting
- Cancelling the meeting.

2.39 If the meeting is postponed or cancelled, the Co-ordinator should consider with the OREC Manager the need to ensure that the applications listed on the agenda are processed within the statutory time limit. If necessary, the applications should be transferred to other RECs.

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Co-opted members

2.40 A REC may co-opt up to two additional members at any meeting of the REC for the purposes of that meeting. A person may be co-opted as a member only if he/she is or has been a member of a REC. Deputy members may not act as co-opted members at their own REC, but may be co-opted by another REC if they have previously been a member of a REC.

2.41 Local procedures for co-opting members within each domain or OREC area are the responsibility of the OREC Manager. The OREC Manager should maintain records of members within the area who would in principle be willing to be co-opted where required. The form of indemnity issued for these members by the appointing authority should clarify that they are indemnified for their actions as co-opted members of other RECs within the domain as well as of the REC to which they are appointed.

2.42 Arrangements should be made to provide a statement of indemnity from the appointing authority, prior to the meeting if possible, in the following cases:

(a) The co-opted member is a former member of a NHS REC, and the indemnity from the appointing authority no longer applies

(b) The co-opted member is a serving member of a NHS REC in another domain, and his/her indemnity does not extend to service on RECs outside the domain.

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Written comments from members

2.43 A member who is unavailable to attend a meeting may submit comments in writing on any agenda item. These should normally be received by the Co-ordinator at least three working days prior to the meeting so that copies may be made available in advance to members. Where later comments are received, they may be tabled at the meeting at the discretion of the Chair. The minutes should record the submission of written comments.

2.44 A member who submits written comments but does not attend the meeting does not count towards the quorum.

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Referees

General policy

2.45 A REC may seek the advice of a referee on any aspects of an application that are relevant to the formation of an ethical opinion, and which lie beyond the expertise of the members or on which the Committee is unable to agree. These referees may be specialists in ethics, specific diseases or methodologies, or they may be representatives of communities, patients or special interest groups.

2.46 Referees are not voting members of the REC, and should not be involved in the business of the Committee other than that related to the application on which their advice is sought.

2.47 The advice of a referee should be sought using one of the following procedures:

(i) The Co-ordinator or Chair may write to the referee seeking *written advice prior to the meeting*. Letter SL4 should normally be used, but where the REC has a regular arrangement with a particular referee a suitable alternative may be used. A copy of the advice received should be made available to members prior to the meeting or tabled at the meeting. The substance of the advice should be recorded in the minutes.

(ii) The Committee may decide at the meeting to seek *written advice following the meeting*. The Co-ordinator or Chair should normally write to the referee within 5 days of the meeting using SL8. The written advice received should then be considered promptly at a meeting of the sub-committee.

(iii) The referee may be invited to *attend the meeting in person* for discussion of the application concerned. The attendance of the referee and the substance of his/her advice at the meeting should be recorded in the minutes. The referee should not personally question the Chief Investigator at the meeting, or have a vote in the decision taken by the Committee.

2.48 The 60 day clock for ethical review does not stop while the advice of a referee is sought (see paragraphs 3.34-3.40).

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CTIMPs involving minors or adults with incapacity

2.49 The REC is required under the Clinical Trials Regulations to obtain advice before giving its opinion on an application relating to a CTIMP in which any subject of the trial is:

(a) a minor, i.e. a person under the age of 16 years

(b) an adult incapable by reason of physical or mental incapacity to give informed consent to participation.

2.50 Where (a) applies and the REC has a member with professional expertise in paediatric care, his/her advice should be obtained on the clinical, ethical and psychosocial problems that may arise in relation to the trial.

2.51 Where (b) applies and the REC has a member with professional expertise in the treatment of the disease to which the trial relates *and* the treatment of the patient population suffering that disease, his/her advice should be obtained on the clinical, ethical and psychosocial problems that may arise in relation to the trial.

2.52 The following procedures apply to applications where either (a) or (b) applies.

2.53 If the relevant member is able to attend the meeting, his/her advice should be considered at the meeting and this should be recorded in the minutes.

2.54 If the relevant member is unable to attend the meeting, he/she should be invited to submit written advice prior to the meeting using SL4 or a suitable alternative. A copy of the advice received should be made available to members prior to the meeting or tabled at the meeting. The substance of the advice should be recorded in the minutes.

2.55 If the REC does not have a suitably qualified member, or the relevant member is unavailable to attend the meeting or to give written advice prior to the meeting, the REC has the following options:

- The Co-ordinator may explore with the OREC Manager whether a suitably qualified member or previous member of another REC may be co-opted.
- The Co-ordinator may explore with CAS whether the application can be transferred to another recognised REC with a suitably qualified member.
- If neither of these courses of action are possible, the REC should proceed with the review but should not give an opinion until it has consulted a referee following the meeting, in accordance with paragraph 2.47(ii).

2.56 For the purposes of this section, a person with professional expertise may be any health care professional or a retired doctor or dentist with relevant expertise.

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Declarations of interest

2.57 Members and deputy members should declare to the Committee any interests they may have in relation to an application for ethical review or any other matter for consideration at that meeting. Such a declaration may be made orally at the meeting, prior to the matter being considered, or in writing to the Chair prior to the meeting.

Applications for ethical review

2.58 Where the member concerned is the Chief Investigator or another key investigator/collaborator named on the application form at A66, the Committee should not proceed with the review, and arrangements should be made urgently for the application to be transferred to another REC.

2.59 In the case of any other declared interest, the Committee should collectively consider whether or not it is appropriate for the member concerned to take any part in the review of the application. Account should be taken of the closeness of the member's interest in the application and the potential for a conflict of interest. In some cases, the declaration of the interest may in itself be sufficient to ensure that the decision of the Committee is not unduly influenced.

2.60 The Committee has the following options:

(i) The member should leave the meeting room and take no part in the discussion or the vote on the application.

(ii) The member may remain in the meeting room in order to provide any relevant information requested by other members, but may not vote.

(iii) The member may remain in the meeting room and take a full part in the review.

2.61 The minutes should record any declaration of interest and the decision of the Committee on the procedure to be followed. If the Committee is in any doubt, it is recommended that the member should leave the meeting room as in paragraph 2.60(i) above.

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Site-specific assessments

2.62 Where a member or deputy member of a local REC is named on the SSI Form as the Principal Investigator or another member of the local research team, the procedures in paragraph 4.51 apply.

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Confidentiality of proceedings

2.63 REC members do not sit on the Committee in any representative capacity and need to be able to discuss freely the applications submitted to them. For this reason REC meetings should be held in private, and members should be encouraged to raise any matters of concern.

2.64 The terms and conditions of appointment for members and deputy members include requirements to keep confidential the business of the REC.

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Observers

2.65 Observers may be invited to attend Committee meetings, subject to written invitation setting out the terms under which observer status is permitted, the signature of a confidentiality agreement, and the agreement of the Committee at the meeting to be attended. Confidentiality agreements should be drawn up using the model in form SF2, which is in line with the duty of confidentiality accepted by REC members.